REMARKS

This responds to the Office Action dated June 27, 2007.

Claims 1 to 25 were acted upon by the Examiner. No claims have been amended. No claims have been canceled. Claims 26 to 32 have been added. Accordingly, claims 1 to 32 are presented for examination.

Reconsideration of the present application in view of the above amendment and following remarks is respectfully requested.

Amendments to the Claims

Support for the new claims 26 to 32 are found in paragraph 0014 of the application which states:

> "While bisoprolol is typically available in racemic form, formulations according to the invention can contain racemic bisoprolol or enantiomers of bisoprolol either as enantiomeric mixtures or as a substantially purified enantiomer. Thus, as used herein, bisoprolol refers to both racemic and enantiomeric forms of bisoprolol."

No new matter has been added to the application.

Summary of the Present Invention

The present invention is directed to new multiparticulate formulations of bisoprolol, including bisoprolol enriched in an enantiomer, for oral administration and, in particular, to a bisoprolol formulation for chronotherapeutic delivery. The chronotherapeutic form can be used for night-time dosing so as to minimise the likelihood of acute cardiovascular occurrences in the well-documented high risk period in the morning.

Summary of the Examiner's Action

Claim Rejections

Claims 1-8 and 10-25 have been rejected on the ground of nonstatutory obviousness-type double patenting over claims 1-7 and 10-25 of Stark, et al. (U.S. Patent No. 6,733,789). The Examiner specifically pointed out that claims 1, 2, 7, 10, and 11 of the present application are not patentably distinct from claims 1, 6, 8, and 9 of the '789 application.

Claims 1 and 9 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Fulberth, et al. (US Patent 3,835,221).

Claims 1 and 9 have been rejected under 35 U.S.C. § 103(a) as being obvious over Stark, et al. (U.S. Patent No. 6,733,789) in view of Fulberth, et al. (US Patent 3,835,221).

Claims 1, 2, 5 and 6 have been rejected under 35 U.S.C. § 103(a) as being obvious over Stark, et al. (U.S. Patent No. 6,733,789).

The Nonstatutory Obviousness-Type Double Patenting Rejections

Claims 1-8 and 10-25 have been rejected on the ground of nonstatutory obviousness-type double patenting over claims 1-7 and 10-25 of Stark, et al. (U.S. Patent No. 6,733,789). Applicants respectfully disagree. Nevertheless, applicants herein sign a terminal disclaimer in compliance with 37 CFR 3.73(b) to overcome the rejection.

The present terminal disclaimer has been signed in order to move prosecution forward as applicants maintain their assertion that the nonstatutory obviousness-type double patenting rejections are improper.

The 35 U.S.C. §102 (b) Rejections

Claims 1 and 9 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Fulberth, et al. (US Patent 3,835,221). With regard to an anticipation rejection, the MPEP §2131 states:

> To anticipate a claim, the reference must teach every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Accordingly, each and every element of the claim being rejected must be found in a single cited prior art. Applicants submit that the present rejection has not satisfied this requirement.

Claim 1 of the present application has "a core of bisoprolol" as an essential element. This element is missing in Fulberth, et al. One might argue that bisoprolol is not essential simply because the claim recites that "each particle comprising a core of bisoprolol or a pharmaceutically acceptable salt." However it should be noted that the later portion of claim 1

demonstrates that "bisoprolol" is essential by reciting "said polymeric coating being effective to achieve an initial lag of bisoprolol release *in vivo* of…." Moreover, bisoprolol is also an essential element for claim 9, wherein the claim specifically recites bisoprolol formulations. On the contrary, Fulberth, et al. never mentions bisoprolol. Accordingly, Fulberth, et al. fails to teach each and every element of claims 1 & 9 of the present application.

In addition, on page 5 of the present office action, he admitted that Fulberth, et al. does not specifically teach the application of a specific active ingredient (i.e. bisoprolol hemifumarate) to the non-pareil seed, but rather teaches that a "single layer of therapeutically active material [is] applied thereto."

For the reasons listed above, the Examiner fails to establish anticipation by Fulberth, et al. and thus, Applicants respectfully request the withdrawal of the rejection.

The 35 U.S.C. §103(a) Rejections

Claims 1, 2, 5, 6 and 9 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Stark, et al. (U.S. patent No. 6,733,789) in view of Fulberth, et al. (U.S. patent No. 3,835,221). Applicants believe that the rejections are improper, and therefore respectfully traverse the rejections.

Applicants submit that Stark, et al. is not prior art under 35 U.S.C. § 102. Applicants respectfully point out that the present application is a continuation under 37 C.F.R. 1.53(b) of a then-pending patent application (Application No. 09/488,103), which later matured into the said Stark, et al. patent. Applicants believe that a priority claim under 35 U.S.C. §119 (e) and §120 has been perfected by complying with the requirements of 37 C.F.R. 1.78(a) on the filing date of the present application. M.P.E.P. §706.02. Thus, Stark, et al. and the present application share the same priority date. Therefore, Stark, et al. should be disqualified as a prior art to the present application.

Once Stark, et al. is disqualified as a prior art under 35 U.S.C. § 102, Applicants respectfully submit that the Examiner fails to establish a *prima facie* obviousness over Fulberth, et al.

With regard to a *prima facie* obviousness rejection, MPEP §2143 states:

> To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.
>
> The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in Applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Accordingly, a proper *prima facie* case of obviousness requires that the combination teach all of the claim limitations. Applicants note that the present rejection has not satisfied this requirement.

Claims 1, 2, 5, 6 and 9 of the present application expressly recite "a multiparticulate bisoprolol formulation." For example, "said polymeric coating being effective to achieve an initial lag of bisoprolol release *in vivo* of at least 4-6 hours following administration…" (Claim 1) and "wherein the polymeric coating is effective to prevent quantifiable bisoprolol plasma concentrations *in vivo*…" (Claim 2). On the other hand, while Fulberth, et al. teaches that a "single layer of therapeutically active material [is] applied thereto," it did not mention bisoprolol at all.

One might argue that "bisoprolol hemifumarate" is covered under the scope of "therapeutically active material' recited in Fulberth, et al. Applicants disagree for the following reasons: First of all, Applicants believe that this proposed genus definition is too broad to be proper. Second, even if "therapeutically active material" could be deemed a proper genus, it does not necessarily render "bisoprolol hemifumarate" obvious. MPEP §2144.08 states:

> The fact that a claimed species or subgenus is encompassed by a prior art genus is not sufficient by itself to establish a *prima facie* case of obviousness. *In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994)

Accordingly, absent a disclosure under Stark, et al. (which is no longer prior art here), the Examiner fails to point out how it becomes obvious for a person with ordinary skill in the art to select "a multiparticulate bisoprolol formulation" as "a specific active ingredient" recited in Fulberth, et al.

For the preceding reason, Applicants believe that Fulberth, et al. fails to teach, either expressly or inherently, all the claim limitations for claims 1, 2, 5, 6 and 9 of the present application. Accordingly, the rejections under 35 U.S.C. § 103(a) are improper. Thus, Applicants respectfully request the withdrawal of the rejection.

A favorable action on the merits is requested respectfully. It is hereby requested that the term to respond to the Office Action dated June 27, 2007, be extended three months, from September 27, 2007 to December 27, 2007. Payment to cover the extension fee has been submitted electronically. The Commissioner is hereby authorized to charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 19-5425.

Respectfully submitted,

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